



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-P-2517]

Determination That MIACALCIN (Calcitonin Salmon) Injection, 100 USP Units/Milliliter (mL), Was Not Withdrawn from Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that MIACALCIN (calcitonin salmon) injection, 100 USP Units/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for calcitonin salmon injection, 100 USP Units/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Donna Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993-0002, 301-796-3600, Donna.Tran@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence

Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, is the subject of NDA 017808, held by Mylan Ireland Ltd., and initially approved on July 3, 1986. MIACALCIN is indicated for: (1) the treatment of symptomatic Paget’s disease of bone in patients with moderate to severe disease characterized by polyostotic involvement with elevated serum alkaline phosphatase and urinary hydroxyproline excretion; (2) early treatment of hypercalcemic emergencies, along with other appropriate agents, when a rapid decrease in serum calcium is required, until more specific treatment of the underlying disease can be accomplished; and (3) treatment of postmenopausal osteoporosis in women greater than 5 years postmenopause.

MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Maiva Pharma Private Ltd. submitted a citizen petition dated October 12, 2022 (Docket No. FDA-2022-P-2517), under 21 CFR 10.30, requesting that the Agency determine whether MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, was voluntarily withdrawn for reasons other than safety or efficacy.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, was not withdrawn for reasons of safety or

effectiveness. The petitioner has identified no data or other information suggesting that MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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